

CLAIMS

1. A factor for treating patients afflicted with a disease that leads to an immunosuppressed state in the patient, which comprises:
≥ 50 kDa fraction of a supernatant derived from lymphocyte cells, which have
5 been subjected to mitogenic stimulation in serum free medium.
2. The factor of claim 1, wherein said lymphocyte cells are lymph node lymphocyte cells.
- 10 3. The factor of claim 1, wherein said mitogenic stimulation includes the presence of Interleukin-2 (IL-2) and anti-CD3 monoclonal antibody.
4. The factor of claim 3, wherein said mitogenic stimulation includes the presence of IL2 and soluble anti-CD3 monoclonal antibody followed by re-
15 stimulation in the presence of insoluble anti-CD3 monoclonal antibody.
5. The factor of claim 1, wherein said lymphocyte cells are peripheral blood lymphocyte cells.
- 20 6. The factor of claim 1 wherein said factor comprises an approximately 70-80 kDa fraction of said 50 kDa fraction.
7. The factor of claim 4, which comprises an approximately 70-80 kDa fraction thereof.
- 25 8. The factor of claim 4, wherein said lymphocyte cells are derived from one or more of a cancer patient, an HIV patient, or a patient free of cancer and HIV.
9. A method for preparing a factor for treating patients afflicted with a disease that leads to an immunosuppressed state in the patient, which comprises the
30 steps of:
 - (a) subjecting cytokine-producing lymphocyte cells to mitogenic stimulation in serum-free media for their expansion;
 - (b) collecting supernatant produced by said mitogenically stimulated cells;

(c) isolating a factor from said supernatant, which comprises a ≥ 50 kDa fraction thereof.

10. The method of claim 9, wherein said disease results from a persistent or acute virus, a bacterial infection, or an autoimmune disease.

11. The method of claim 10, wherein said persistent or acute virus is an enveloped or non-enveloped RNA or DNA virus.

12. The method of claim 11, wherein said persistent or acute RNA virus is selected from one or more of picornaviruses, togaviruses, paramyxoviruses, orthomyxoviruses, rhabdoviruses, reoviruses, retroviruses, bunyaviruses, coronaviruses, and arenaviruses.

13. The method of claim 11, wherein said persistent or acute DNA virus is selected from one or more of parvoviruses, papoviruses, adenoviruses, herpesviruses, and poxviruses.

14. The method of claim 10, wherein said disease is one or more of chronic fatigue syndrome (CFS), tuberculosis, measles, dengue fever, malaria, hepatitis (chronic), leprosy, rheumatoid arthritis, multiple sclerosis, or canine distemper virus.

15. The method of claim 10, wherein said disease comprises chronic fatigue syndrome (CFS).

16. The method of claim 9, wherein said disease is cancer.

17. The method of claim 16, wherein said cancer is an adenocarcinoma.

18. The method of claim 9, wherein said lymphocyte cells are one or more of lymph node lymphocyte cells (LNL) or peripheral blood lymphocyte cells (PBL).

19. The method of claim 9, wherein said mitogenic stimulation includes the presence of Interleukin-2 (IL-2) and anti-CD3 monoclonal antibody.
- 5 20. The method of claim 19, wherein said mitogenic stimulation includes the presence of IL2 and soluble anti-CD3 monoclonal antibody followed by re-stimulation in the presence of insoluble anti-CD3 monoclonal antibody.
- 10 21. The method of claim 20, wherein said isolate of step (c) is subjected to separation to recover an approximately 70-80 kDa fraction thereof, which is said factor.
22. The method of claim 21, wherein said disease results from a persistent or acute virus, a bacterial infection, a parasite, or an autoimmune disease.
- 15 23. The method of claim 22, wherein said persistent or acute virus in an enveloped or non-enveloped RNA or DNA virus.
- 20 24. The method of claim 23, wherein said persistent or acute RNA virus is selected from one or more of picornaviruses, togaviruses, paramyxoviruses, orthomyxoviruses, rhabdoviruses, reoviruses, retroviruses, bunyaviruses, coronaviruses, and arenaviruses.
- 25 25. The method of claim 23, wherein said persistent or acute DNA virus is selected from one or more of parvoviruses, papoviruses, adenoviruses, herpesviruses, and poxviruses.
- 30 26. The method of claim 22, wherein said disease is one or more of chronic fatigue syndrome (CFS), tuberculosis, measles, dengue fever, malaria, hepatitis (chronic), leprosy, rheumatoid arthritis, multiple sclerosis, and canine distemper virus.
27. The method of claim 22, wherein said disease comprises chronic fatigue syndrome (CFS).

28. The method of claim 21, wherein said disease is cancer.
29. The method of claim 28, wherein said cancer is an adenocarcinoma.
- 5 30. The method of claim 21, wherein said lymphocyte cells are one or more of lymph node lymphocyte cells (LNL) or peripheral blood lymphocyte cells (PBL).
31. The method of claim 21, wherein said mitogenic stimulation includes the presence of Interleukin-2 (IL-2) and anti-CD3 monoclonal antibody.
- 10 32. The method of claim 29, wherein said mitogenic stimulation includes the presence of IL2 and soluble anti-CD3 monoclonal antibody followed by re-stimulation in the presence of insoluble anti-CD3 monoclonal antibody.
- 15 33. Method for enhancing the activity of one or more of topoisomerase I, topoisomerase II, microtubule, or thymidylate synthetase active agent, which comprises: combining said active agent with a factor, which comprises a ≥ 50 kDa fraction of a supernatant derived from lymphocyte cells, which have been subjected to mitogenic stimulation in serum free medium.
- 20 34. The method of claim 33, wherein said active agent is one ore more of 5-flurouracil, doxorubicin HCl, etoposide phosphate, irinotecan, or gemcitabine HCl.
- 25 35. The method of claim 33, wherein said factor is an approximately 70-80 kDa fraction of said ≥ 50 kDa fraction.
36. Method for enhancing the activity of tamoxifen, which comprises: combining said tamoxifen with a factor, which comprises a ≥ 50 kDa fraction of a supernatant derived from lymphocyte cells, which have been subjected to mitogenic stimulation in serum free medium.
- 30 37. The method of claim 36, wherein said factor is an approximately 70-80 kDa fraction of said ≥ 50 kDa fraction.

38. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 1.
39. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 2.
40. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 3.
41. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 4.
42. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 5.
43. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 6.
44. A method for treating patients afflicted with human immunodeficiency virus (HIV), which comprises:
administering to said patient an effective dosage of the factor of claim 7.
45. A method for treating patients afflicted with a disease that leads to an immunosuppressed state in the patient, which comprises:
administering to said patient an effective dosage of the factor of claim 1.

46. The method of claim 45, wherein said factor is an approximately 70-80 kDa fraction of said ≥ 50 kDa fraction.
47. The method of claim 45, wherein said disease results from a persistent or acute virus, a bacterial infection, or an autoimmune disease.
48. The method of claim 47, wherein said persistent or acute virus is an enveloped or non-enveloped RNA or DNA virus.
49. The method of claim 48, wherein said persistent or acute RNA virus is selected from one or more of picornaviruses, togaviruses, paramyxoviruses, orthomyxoviruses, rhabdoviruses, reoviruses, retroviruses, bunyaviruses, coronaviruses, and arenaviruses.
50. The method of claim 48, wherein said persistent or acute DNA virus is selected from one or more of parvoviruses, papoviruses, adenoviruses, herpesviruses, and poxviruses.
51. The method of claim 45, wherein said disease is one or more of chronic fatigue syndrome (CFS), tuberculosis, measles, dengue fever, malaria, hepatitis (chronic), leprosy, rheumatoid arthritis, multiple sclerosis, and canine distemper.
52. The method of claim 46, wherein said disease results from a persistent or acute virus, a bacterial infection, or an autoimmune disease.
53. The method of claim 46, wherein said persistent or acute virus is an enveloped or non-enveloped RNA or DNA virus.
54. The method of claim 53, wherein said persistent or acute RNA virus is selected from one or more of picornaviruses, togaviruses, paramyxoviruses, orthomyxoviruses, rhabdoviruses, reoviruses, retroviruses, bunyaviruses, coronaviruses, and arenaviruses.

55. The method of claim 53, wherein said persistent or acute DNA virus is selected from one or more of panoviruses, papoviruses, adenoviruses, herpesviruses, and poxviruses.
- 5 56. The method of claim 46, wherein said disease is one or more of chronic fatigue syndrome (CFS), tuberculosis, measles, dinghy fever, malaria, hepatitis (chronic), leprosy, rheumatoid arthritis, multiple sclerosis, and canine distemper.
- 10 57. A factor for treating a patient afflicted with a disease that leads to an immunosuppressed state in the patient, wherein said factor comprises a protein whose active form has a molecular weight greater than 50 kDa, said protein being derived from lymphocyte cells which have been subjected to mitogenic stimulation.
- 15 58. The factor of claim 57, wherein said lymphocyte cells are lymph node lymphocyte cells.
59. The factor of claim 57, wherein said mitogenic stimulation includes the presence of Interleukin-2 (IL-2) and anti-CD3 monoclonal antibody.
- 20 60. The factor of claim 59, wherein said mitogenic stimulation includes the presence of IL2 and soluble anti-CD3 monoclonal antibody followed by re-stimulation in the presence of insoluble anti-CD3 monoclonal antibody.
- 25 61. The factor of claim 57, wherein said lymphocyte cells are peripheral blood lymphocyte cells.
62. The factor of claim 57 wherein the active form of said protein has a molecular weight of approximately 70- 80 kDa.
- 30 63. The factor of claim 60 wherein the active form of said protein has a molecular weight of approximately 70- 80 kDa.

64. The factor of claim 57, wherein said lymphocyte cells are derived from one or more of a cancer patient, an HIV patient, or a patient free of cancer and HIV.
65. The factor of claim 57, wherein the active form of said protein is a multimer.
- 5 66. The factor of claim 60, wherein the active form of said protein is a multimer.

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